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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,928	03/23/2005	Marc Hubert Mercken	PRD-0032-USPCT1	4646

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EXAMINER	
WANG, CHANG YU	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,928	MERCKEN ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/07 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 9/17/07 is acknowledged. Claims 1, 12 and 13 are cancelled. Claims 2-11 and 14-16 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 10/15/07 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Maintained

In view of the amendment filed on 9/17/07, the following rejections are maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5, 8, 9, 11 and 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383), Pirttila et al. (J. Neurol Sci. 1994 Dec 1; 127:90-5), WO0162801 (as in IDS submitted on Mar 23, 2005) or Näslund et al (as in IDS submitted on Mar 23, 2005). The rejection is maintained for the reasons made of record in the office mailed on 4/17/07, and as follows.

At p. 6-7 of the response, Applicant argues that Walker et al., Pirtila, WO0162801 and Naslund do not dislcose antibodies that bind to Ab11-x without cross-reacting with the full length of Ab1-40/42 as presently claimed. Applicant's arguments have been fully considered but they are not persuasive.

In response, as previously made of record, the art antibodies raised against Aβ1-16 (Walker and Naslund), Aβ17-24 (Prittila), and Aβ13-28 (WO01/62801) immungens can bind to the epitopes of Aβ11-x as evidenced by Huse et al (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284, cited in the previuos office action). With regard to whether the art antibodies have the same property as the claimed antibodies that bind to Ab11-x without cross reacting with the full length of Ab1-40/42, it is noted that Applicant claims

a product in terms of a function, property or characteristics is the same as the prior art products.

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

In addition, if the epitope to which Applicant's antibody binds is present in Aβ11-x, so that Applicant's antibody binds to Aβ11-x, it is also present in Aβ 1-16, 17-24, and 13-28.

"There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); Abbott Labs v. Geneva Pharms., Inc., 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999)".

Thus, that the art did not recognize that antibodies binding to sequences overlapping (Aβ 11-16, 1-28 and 8-17) with residues Aβ11-17 or Aβ11-15 (i.e. SEQ ID NOs: 1-4 recited in the claims) were inherently binding to an epitope contained within Aβ11-17 or Aβ11-15 (SEQ ID NOs:1-4) does not render the antibodies binding to the epitope novel.

In addition,

"When an examiner obtains a product which reasonably appears to fall within the scope of that which is claimed by a patent applicant, it is reasonable to shift the burden to the applicant to provide evidence showing that the product of the prior art does not fall within the scope of applicants' [sic] claims." see Ex parte Maizel, 27 USPQ2d 1662, 1667-68 (Bd. Pat. App. Int. 1992).

It is known in the art that anti-Aβ antibodies can cross react with different species or

different lengths of Aβ peptides in different titrations because of their different binding affinity. Applicant has provided no showing that the antibodies in the art have characteristics different from those specifed by Applicant and do not in fact cross react with the full length of Aβ1-40/42 in the same titration or at the same concentration.

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

6. Claims 2, 5, 8, 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Solomon et al. (Proc. Natl. Acad. Sci. USA. 1996. 93: 452-455). Claims 2, 5, 8, and 14-16 stand rejected under 35 U.S.C. 102 (a) as being anticipated by Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284). The rejections are maintained for reasons made of record in the office action on 4/17/07, and as follows.

At p. 7 of the response, Applicant argues that the reference of Solomon et al. is silent on an antibody as presently claimed which detects Aβ11-x while being negative for Ab1-40/42 peptide. Applicant's arguments have been fully considered but they are not persuasive.

In response, as previously made of record, the antibodies raised against aa 1-28 and 8-17 taught by Solomon et al. would inherently recognize Aβ11-x because the amino acid sequence of the immunogens (5-7 amino acids of Aβ11-x) for the instant antibodies are encompassed in the sequences of amino acids 1-28 and 8-17 of Aβ. For the same reason, the antibody BNT77 taught by Huse et al. was raised against amino acids 11-16 of Aβ, thus it can recognize N-terminal truncated species of Aβ.

It is known in the art that anti-Abeta antibodies can cross react with different species or length of Aβ peptides in different titrations. Applicant has provided no showing that the antibodies in the art have characteristics different from those specifed by Applicant and do not in fact cross react with the full length of Aβ1-40/42 in the same titration. In addition, if the epitope to which Applicant's antibody binds is present in Aβ11-x, so that Applicant's antibody binds to Aβ11-x, it is also present in Aβ 11-16, 1-28 and 8-17.

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5, 8, 9, 11 and 14-16 under 35 U.S.C. 103(a) for being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action). The rejection is maintained for the reasons made of record in the office action mailed on 4/17/07, and as follows.

At p. 8 of the response, Applicant argues that Huse et al. do not teach the claimed invention because the antibodies disclosed by Huse et al. can detect the full length of Aβ peptide and the combined references do not disclose or suggest the claimed antibodies specific for Aβ11-x peptides. Applicant's arguments have been fully considered but they are not persuasive.

In response, for the reasons set forth above in the section of the rejection under USC 35 102 (see paragraphs 5-6), the antibodies disclosed by Huse et al., Walker et al. and WO0162801 do recognize Aβ11-x because the antibodies disclosed Huse et al., Walker et al. and WO0162801 have been shown to have the same property as the claimed antibodies. In addition, WO0162801 also teaches a method of detection of Aβ in the brain tissue and CSF of Alzheimer's disease patients using labeled antibodies by electrophoresis or ELISA as recited in claims 9-11 and 14 (see p.26, examples 1-2; p. 30, example 6). Thus, It would have been obvious to one of ordinary skill in the art at

the time the instant invention was made to use the antibody raised against Aβ11-16 or use the antibody that can recognize Aβ11-x to detect Aβ11-x in Alzheimer's disease because the level of Aβ11-40/42 has been shown increased in AD patients. The person of ordinary skill in the art would have been motivated and have expected success in using an antibody that recognize Aβ11-x to detect diseases associated Aβ formation because the antibody against Aβ11-16 is able to detect Aβ11-40/42 in AD brains.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on 10/15/07.

Claim Objections

8. Claims 3, 5, 6, 8, 14 and 15 are objected to because of the following informalities: Claims 3, 5, 6, 8, 14 and 15 depend from claim 1. However, claim 1 is canceled. The claims 3, 5, 6, 8, 14 and 15 are interpreted as depending from claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of Aβ11-40 in the CSF and brain section

of Alzheimer's disease by using antibodies raised against Aβ peptides consisting of 6-8 amino acids of Aβ_11 (6AA) or Aβ_(8AA) (SEQ ID NOs: 1-4), does not reasonably provide enablement for using the antibodies that specifically bind to Aβ11-x peptides to diagnose all amyloid-related diseases as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is reinstated and maintained for the reasons made of record in the office action mailed 09/07/06, and as follows.

As previously made of record, although Applicant is able to detect Aβ11-40 in AD, different Aβ N-terminal variants are also found in human amyloid plaques including Aβ1-x, Aβ3-x, Aβ11-x and Aβ17-x and so are Aβx-42 and Aβx-40 (see p. 241, abstract, Tekirian J. Alzheimers Dis. 2001. 3: 241-248, cited). In addition, it is still not clear whether the N-terminal truncated forms of Aβ especially pryoglutamylated Aβpy11-42 is the cause of AD in AD patients with presenilin-1 mutation because detectable Aβ1-42 is more abundant than detectable Aβpy11-42 in plaques, which argues against the pathogenic role of Aβ11-42 (see p. 343. Larner. Neurobiol. Aging. 2001. 22: 343, cited in a prior office action). It is unpredictable whether detection of Aβ11-40 can be used to detect/diagnose all of the diseases associated with production of b-amyloid peptides since multiple forms of Aβ variants are present in amyloid deposits and Aβ1-42 is more abundant than Aβ11-40; and Aβ11-140 is also detectable in control as shown in the specification (see p. 23, line 25). Furthermore, the claims recite "diagnosis of diseases

associated with production of b-amyloid peptides". However, the specification fails to provide sufficient guidance as to what other diseases are associated with production of b-amyloid peptides and thus a skilled artisan would not know whether detection of Aβ11-42 or Aβ11-40 by the claimed antibodies can be used to diagnose all forms of diseases associated with β-amyloid production since it is unclear what other diseases associated with β-amyloid production are. Moreover, it is unpredictable whether the claimed antibodies can be used to diagnose other diseases associated with production of amyloid peptides because it is unknown whether Aβ11-40 can be found in other diseases associated with production of β-amyloid peptides other than AD. Therefore, in view of the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, undue experimentation would be required of a skilled artisan to practice the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claim14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: no detective step and no step of determination. The claim as recited fails to teach how to detect and how to determine whether a subject having diseases associated with production of β-amyloid peptides.

recite claim 1 so these claims (which are originally derived from claim 1) could be derived from any claim, and this makes the claims unclear to the examiner. Claims 3, 5, 6, 8, 14 and 15 are interpreted as depending from claim 2.

Claim 16 is indefinite because the claim recites "support". Applicant describes several possibilities of carrier on p. 9, line 21. However, the description is not definite because Applicant fails to define/describe what is encompassed in the definition of "support". The disclosure fails to set forth the metes and bounds of what is encompassed within the definition of such support; thus the claim is indefinite.

11. Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-6 are indefinite because the claims recite "a" while depending from an independent base claim. The article "A" connotes that there is more than a single method or product encompassed within the base claim and since only a single method or product was set forth therein, it is unclear what, if any, additional methods or products are encompassed.

Claim Rejections - 35 USC § 102/103

12. Claims 2, 6, 7, 15 and 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6984720 (Korman et al. issued on Jan 10, 2006, priority Aug 24, 1999).

US Patent No. 6984720 (the '720 patent) teaches a monoclonal antibody produced by a hybridoma cell line 5C4 that can block amyloid accumulation in Alzheimer's patients (see col.9, lines 47-62.). Although the '720 patent is silent with regard to binding to Aβ11-x, the monoclonal antibody is generated from a hybridoma cell line 5C4. The hybridoma cells J&JPRD/hAβ11/2 as recited in instant claims 6-7 are also named 5C4 (see p. 22, line 29). Note that

"The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). " See MPEP § 2112.01 [R-3].

In addition, the intended use as recited in claims 15 and 16 are not given patentable weight since the antibody generated from the hybridoma 5C4 has the same property.

Therefore, Claims 2, 6, 7, 15 and 16 are anticipated by or unpatentable over US Patent No. 6984720

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA1977)." See MPEP § 2112 [R-3]

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

Claim Rejections - 35 USC § 103

13. Claims 2-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. (Huse et al. J. Biol. Chem. 2002. 277: 16278-16284) in view of Walker et al (J. Neuropathol. Exp. Neurol.1994 Jul. 53: 377-383 as cited in the previous office action) and WO0162801 (as in IDS submitted on Mar 23, 2005 and cited in the previous office action) as applied to claims 2-5, 8, 9, 11 and 14-16 above, and further in view of US Patent No. 6984720 (Korman et al. issued on Jan 10, 2006, priority Aug 24, 1999).

Huse et al., Walker et al., and WO0162801 are as set forth above at paragraphs 6-7 but fail to J&JPRD/hAβ11/1 and J&JPARD/hAβ11/2 as recited in instant claims 6-7 and 10.

US Patent No. 6984720 teaches a hybridoma 5C4, which is J&JPARD/hAβ11/2 as recited in instant claims 6-7 and 10.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to generate an antibody raised against Aβ11-15 or 11-17 (SEQ ID NO:1-4) to substitute the antibodies of Huse et al., Walker et al., and WO0162801 by a hybridoma 5C4 (J&JPARD/hAβ11/2) as in instant claims 6-7 because the antibody of the hybridoma 5C4 can reduce amyloid accumulation and antibodies against Aβ 1-16, 11-16, 1-28 and 8-17 can bind Aβ11-x. It would also have been obvious to one of ordinary skill in the art at the time the instant invention was made to substitute the antibodies of Huse et al., Walker et al., and WO0162801 by a hybridoma 5C4 (J&JPARD/hAβ11/2) in the methods of detecting or diagnosing AD to detect Aβ11-

x in AD as recited in instant claim 10 because the antibody of the hybridoma 5C4 can reduce amyloid accumulation and the level of Aβ11-40/42 has been shown increased in AD patients. The person of ordinary skill in the art would have been motivated to do so because the antibody of the hybridoma 5C4 has been shown to be able to reduce amyloid accumulation in AD and antibodies of Huse et al., Walker et al., and WO0162801 binding to Aβ11-x, and Aβ11-40/42 can be found in AD brains. Thus, one of ordinary skill in the art would have expected success in generating an antibody against the amino acids 5-7 of Aβ11-x or an antibody of the hybridoma 5C4 (J&JPARD/hAβ11/2) and using the antibody to detect Aβ11-40/42 in AD patients.

Conclusion

14. NO CLAIM IS ALLOWED.

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
December 26, 2007

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud